

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

GREGORY KLINE and CHERRIE KLINE,)	
Plaintiffs,)	
)	
vs.)	Civil Action No. 13-513
)	
ZIMMER HOLDINGS, INC., ZIMMER, INC.)	
and ZIMMER US, INC.,)	
Defendants.)	

REPORT AND RECOMMENDATION

I. Recommendation

It is respectfully recommended that the partial motion to dismiss filed on behalf of the defendants (ECF No. 12), treated as a partial motion for judgment on the pleadings, be granted in part and denied in part as follows: as to the strict liability claims in Count II, the motion should be granted with respect to Plaintiffs' design defect and failure to warn claims, but denied with respect to Plaintiffs' manufacturing defect claim; as to the breach of implied warranties claims in Count III, the motion should be granted with respect to Plaintiffs' claim of breach of the implied warranty of fitness for a particular purpose and the claim of breach of implied warranty of merchantability based upon the design defect and failure to warn claims, but denied with respect to Plaintiffs' claim of breach of the implied warranty of merchantability based upon a manufacturing defect; as to the breach of express warranties claims in Count IV, the motion should be granted.

II. Report

Plaintiffs, Gregory Kline and his wife Cherrie Kline, bring this action alleging claims of negligence, strict liability, breach of express warranties, breach of implied warranties and loss of consortium, arising out of injuries sustained by Gregory Kline from an allegedly defective hip replacement component manufactured by Defendants, Zimmer Holdings, Inc., and/or its wholly-

owned subsidiaries, Zimmer, Inc. and Zimmer US, Inc. (together, “Zimmer”).

Presently pending before the Court is a partial motion to dismiss, filed by Defendants. Specifically, they seek to dismiss the claims alleged in Count II (strict liability), Count III (breach of implied warranties), and Count IV (breach of express warranties) and to limit the loss of consortium claim in Count V. For the reasons that follow, the motion should be granted in part and denied in part.

Facts

On January 13, 2010, Gregory Kline, who suffered from degenerative joint disease of the right hip, was admitted to Allegheny General Hospital for hip replacement surgery, which was performed by Dr. Nicholas G. Sotereanos that same day. (Compl. ¶¶ 10-11.) Dr. Sotereanos implanted a Zimmer M/L Taper Femoral Stem, manufactured by Defendants. The subject implant consisted of two separate components: a modular stem, which is inserted into the femur; and a neck, which is joined together with the stem in the manufacturing process. From all indications, the surgery was a success. (Compl. ¶ 12.)

On April 6, 2011, Mr. Kline stepped down two or three feet from the back of a truck to the sidewalk and immediately felt pain in his right leg and was unable to walk. He was transported to Allegheny General Hospital and seen by Dr. Sotereanos, who determined that the Zimmer implant had snapped at the joint between the neck and the stem. (Compl. ¶¶ 15-18.) The fracture was consistent with a fatigue crack, caused by stress and corrosion. (Compl. ¶ 20.) On April 11, 2011, Mr. Kline underwent a six and one-half hour operation by Dr. Sotereanos to remove the faulty Zimmer implant and insert a new one. (Compl. ¶¶ 21-28.)

Procedural History

Plaintiffs filed this action in the Court of Common Pleas of Allegheny County,

Pennsylvania on March 15, 2013. Count I alleges that Defendants were negligent in the preparation, design, research, development, manufacture, inspection, labeling, marketing, promotion and sale of the hip implant components and that this negligence caused Mr. Kline's injury. Count II alleges claims of strict liability based on design defects, manufacturing defects and a failure to warn. Count III alleges claims of breach of the implied warranties of merchantability and fitness for a particular purpose. Count IV alleges a claim of breach of express warranties. Count V alleges a derivative claim of loss of consortium on behalf of Cherrie Kline.

On April 9, 2013, Defendants removed the case to this Court, asserting diversity of citizenship jurisdiction in that: Plaintiffs are Pennsylvania citizens; Zimmer is a Delaware corporation with its principal place of business in Warsaw, Indiana; and the amount in controversy, exclusive of interest and costs, exceeds the sum of \$75,000.00. (Notice of Removal ¶¶ 7-15.) On April 12, 2013, Defendants filed an answer to the complaint (ECF No. 7). On May 3, 2013, they filed a partial motion to dismiss (ECF No. 12).¹ On May 22, 2013, Plaintiffs filed a brief in opposition to the motion (ECF No. 18) and on May 31, 2013, Defendants filed a reply brief (ECF No. 19).

Standard of Review

The Supreme Court has issued two decisions that pertain to the standard of review for a motion to dismiss for failure to state a claim upon which relief could be granted under Federal Rule of Civil Procedure 12(b)(6). The Court held that a complaint must include factual allegations that "state a claim to relief that is plausible on its face." Ashcroft v. Iqbal, 556 U.S.

¹ Because they had already filed an answer, the motion is properly designated a partial motion for judgment on the pleadings under Federal Rule of Civil Procedure 12(c). Nevertheless, as explained herein, the standard of review is the same.

662, 678 (2009) (citing Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). “[W]ithout some factual allegation in the complaint, a claimant cannot satisfy the requirement that he or she provide not only ‘fair notice’ but also the ‘grounds’ on which the claim rests.” Phillips v. County of Allegheny, 515 F.3d 224, 232 (3d Cir. 2008). In determining whether a plaintiff has met this standard, a court must reject legal conclusions unsupported by factual allegations, “[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements;” “labels and conclusions;” and “‘naked assertion[s]’ devoid of ‘further factual enhancement.’” Iqbal, 556 U.S. at 678 (citations omitted). Mere “possibilities” of misconduct are insufficient. Id. at 679. District courts are required to engage in a two part inquiry:

First, the factual and legal elements of a claim should be separated. The District Court must accept all of the complaint’s well-pleaded facts as true, but may disregard any legal conclusions.... Second, a District Court must then determine whether the facts alleged in the complaint are sufficient to show the plaintiff has a “plausible claim for relief.” ... In other words, a complaint must do more than allege the plaintiff’s entitlement to relief. A complaint has to “show” such an entitlement with its facts.

Fowler v. UPMC Shadyside, 578 F.3d 203, 210-11 (3d Cir. 2009) (citations omitted).

A motion for judgment on the pleadings under Rule 12(c) is treated in the same manner as a motion to dismiss for failure to state a claim upon which relief may be granted. The court should “accept the truth of all factual allegations in the complaint and must draw all reasonable inferences in favor of the non-movant.” Revell v. Port Auth. of NY& NJ, 598 F.3d 128, 134 (3d Cir. 2010) (citing Turbe v. Government of the V.I., 938 F.2d 427, 428 (3d Cir. 1991)).

Defendants contend that: 1) Count II should be dismissed because, under Pennsylvania law, Plaintiffs cannot state a claim for strict liability against a manufacturer of a prescription medical device; 2) Count II should be dismissed because claims of breach of implied warranties against manufacturers of prescription medical devices are also barred; 3) Count IV should be

dismissed because it fails to allege facts sufficient to suggest a plausible right to relief for breach of express warranties and because, in the absence of an identified promise or representation, the claims are essentially claims for breach of implied warranties, which are barred; and 4) the loss of consortium claim in Count V, to the extent that it is derivative of Counts II, III and IV, should be limited accordingly upon the dismissal of these counts.

Plaintiffs respond that: 1) under Pennsylvania law, a plaintiff may state a claim for strict liability against the manufacturer of a prescription medical device based upon a manufacturing defect; 2) under Pennsylvania law, a plaintiff may state a claim for breach of implied warranties against the manufacturer of a prescription medical device based upon a manufacturing defect; and 3) they have alleged sufficient facts to state a claim for breach of express warranties.

Strict Liability Claims

In Count II, Plaintiffs allege claims of strict liability. Defendants move to dismiss these claims on the grounds that they are barred under Pennsylvania law. Plaintiffs respond that claims of strict liability arising out of manufacturing defects are not barred.

A federal court sitting in diversity must apply the substantive law of the state in which it sits, Erie R.R. Co. v. Tompkins, 304 U.S. 64, 78 (1938), including its choice of law rules, Klaxon Co. v. Stentor Elec. Mfg. Co., 313 U.S. 487, 496. Defendants assert that there is no choice of law question presented and that Pennsylvania law applies to this case. (ECF No. 13 at 4 n.2.) Plaintiffs cite only Pennsylvania cases, as will the Court.

Pennsylvania law recognizes three different types of defects that can give rise to a strict-liability claim: a design defect, a manufacturing defect, and a failure to warn defect. See Phillips v. A-Best Prods. Co., 665 A.2d 1167, 1170 (Pa. 1995). In this case, Plaintiffs allege all three theories of strict liability.

“Strict liability allows a plaintiff to recover where a product in ‘a defective condition unreasonably dangerous to the user or consumer’ causes harm to the plaintiff.” Id. (quoting § 402A of the Restatement (Second) of Torts). Comment k of Section 402A, however, limits liability for “unavoidably unsafe” products, such as prescription drugs. See Restatement (Second) of Torts § 402A cmt. k (1965). The comment recognizes that “[t]here are some products, which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use,” and provides that such a product, “properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous.” Adopting and applying comment k, the Pennsylvania Supreme Court has held that, “assuming proper preparation and warning, a manufacturer of [prescription] drugs is not strictly liable for unfortunate consequences attending the use of otherwise useful and desirable products which are attended with a known but apparently reasonable risk.” Hahn v. Richter, 673 A.2d 888, 890-91 (Pa. 1996) (citations omitted).

Although the Pennsylvania Supreme Court has addressed the application of comment k only in the context of prescription drugs, the Superior Court has applied comment k to prescription medical devices, “find[ing] no reason why the same rational[e] applicable to prescription drugs may not be applied to medical devices.” Creazzo v. Medtronic, Inc., 903 A.2d 24, 31 (Pa. Super. 2006). Similarly, a number of federal courts have predicted that the Pennsylvania Supreme Court would extend comment k to prescription medical devices. See Esposito v. I-Flow Corp., 2011 WL 5041374, at *4 (E.D. Pa. Oct. 24, 2011); Geesey v. Stryker Corp., 2010 WL 3069630, at *3-4 (E.D. Pa. Aug. 4, 2010); Soufflas v. Zimmer, Inc., 474 F. Supp. 2d 737, 750 (E.D. Pa. 2007); Davenport v. Medtronic, Inc., 302 F. Supp. 2d 419, 441-42 (E.D. Pa. 2004); Parkinson v. Guidant Corp., 315 F. Supp. 2d 741, 747 (W.D. Pa. 2004)

(Diamond, J.) (agreeing “with the district courts in the Eastern District of Pennsylvania that the same considerations exempting prescription drugs from the ambit of § 402A equally apply to prescription medical devices”). Plaintiffs do not argue that comment k does not apply to prescription medical devices.

The Pennsylvania Superior Court has explained that “[w]ith our Supreme Court’s adoption of comment k, a design defect claim for strict liability is not cognizable under Pennsylvania law when it is asserted against a manufacturer of prescription drugs.” Lance v. Wyeth, 4 A.3d 160, 165 (Pa. Super. 2010), appeal granted on other grounds, 15 A.3d 429 (Pa. 2011). Moreover, with respect to failure to warn claims, the Pennsylvania Supreme Court has made it clear that strict liability does not apply and that “negligence is the only recognized basis for recovery.” Hahn, 673 A.2d at 889. As the court explained, “where the adequacy of warnings associated with prescription drugs is at issue, the failure of the manufacturer to exercise reasonable care to warn of dangers, i.e., the manufacturer’s negligence, is the only recognized basis of liability.” Id. at 891.

However, the Pennsylvania Supreme Court has not extended its application of comment k to manufacturing defect claims. Several district courts have applied the Hahn case broadly to bar manufacturing design claims. See Gross v. Stryker Corp., 2012 WL 876719, at *8-9 (W.D. Pa. Mar. 14, 2012) (Fischer, J.); Horsmon v. Zimmer Holdings, Inc., 2011 WL 5509420, at *2 (W.D. Pa. Nov. 10, 2011) (Bissoon, M.J.); Soufflas, 474 F. Supp.2d at 748-50; Parkinson, 315 F. Supp. 2d at 747-48; Davenport, 302 F. Supp. 2d at 441-42. However, as aptly observed by a district court in a recent thorough discussion of the issue, these courts did not address the “properly prepared” requirement in comment k or otherwise distinguish among design-defect, manufacturing-defect and failure-to-warn claims in concluding that strict-liability claims against

manufacturers of prescription drugs and devices are not cognizable under Pennsylvania law. Dougherty v. C.R. Bard, Inc., 2012 WL 2940727, at *4 (E.D. Pa. July 18, 2012). Judge Yohn noted that, in the Lance case, the Superior Court did not read any of the state cases as barring strict-liability manufacturing-defect claims against a manufacturer of prescription drugs or devices, and he did not do so either.

Recently, Judge Conti concluded that:

the magistrate judge properly relied upon the rationale set forth in Dougherty v. C.R. Bard, Inc., C.A. No. 11–6048, 2012 WL 2940727 (E.D. Pa. July 18, 2012), where, after a thorough analysis of Hahn, the district judge found that while Hahn instructs that strict liability applies to failure [to] warn claims, comment k’s exemption from strict liability does not extend to manufacturing defects. Id. at *6, 673 A.2d 888. At this preliminary stage of the litigation, Plaintiff’s allegations in paragraph 48(a), (d), (i) and (j) of the complaint sufficiently allege a manufacturing defect claim in strict liability. Accordingly, the motion to dismiss with respect to the strict liability manufacturing claim in this case was properly denied.

Killen v. Stryker Spine, 2012 WL 4498865, at *4 (W.D. Pa., Sep. 28, 2012) (Conti, J.).

Defendants cite Kester v. Zimmer Holdings, Inc., 2010 WL 2696467 (W.D. Pa. June 16, 2010) (McVerry, J.), as a case barring a strict liability claim against a medical device manufacturer. However, the claim in that case was based solely on a failure to warn theory. Id. at *9. Thus, it does not support the argument that a manufacturing defect claim is barred.

They also contend that both Killen and Dougherty are “unpublished” decisions that are not binding or persuasive authority. However, district court cases, which are not binding authority but may be examined for their persuasiveness, are not rendered more or less persuasive based on whether they appear in a bound West reporter or an electronic database (which is what Defendants call “unpublished”). See Smith v. Astrue, 639 F. Supp. 2d 836, 841-42 (W.D. Mich. 2009); National Union Fire Ins. Co. of Pittsburgh, Pa. v. BP Amoco P.L.C., 319 F. Supp. 2d 352, 362 n.6 (S.D.N.Y. 2004); Manley v. The Horsham Clinic, 2001 WL 894230, at *4 & n.2 (E.D.

Pa. Aug. 9, 2001). Many of the decisions cited by Defendants are also “unpublished.” In addition, it is noted that Judge Conti, the district judge in Killen, is also the district judge in this case. Thus, if Defendants’ argument is accepted, the result would be that Judge Conti would issue inconsistent decisions on this legal issue.

In this case, which is very similar to Killen, the allegations of paragraph 42(c), (d), (h), (i) and (j) are sufficient to state a claim for a manufacturing defect strict liability claim relating to the hip replacement component, a prescription medical device, and such a claim is permitted under Pennsylvania law. Therefore, with respect to Count II, the motion to dismiss should be granted with respect to Plaintiffs’ strict liability design defect and failure to warn claims, but denied with respect to Plaintiffs’ strict liability manufacturing defect claim.

Breach of Implied Warranties

In Count III, Plaintiffs allege claims of breaches of the implied warranties of merchantability and fitness for a particular purpose. Defendants argue that, under Pennsylvania law, such claims are barred. Plaintiffs respond that claims based upon manufacturing defects are not barred.

The implied warranty of merchantability arises by operation of law, 13 Pa. C.S. § 2314, and “serves to protect buyers from loss where goods purchased are below commercial standards.” Dougherty, 2012 WL 2940727, at*6 (citation omitted). Several district court decisions have concluded that comment k of the Restatement precludes claims for breach of the implied warranty of merchantability against manufacturers of prescription drugs and devices. See Kester, 2010 WL 2696467, at *11; Soufflas, 474 F. Supp. 2d at 751-52; Parkinson, 315 F. Supp. 2d at 752-53; Davenport, 302 F. Supp. 2d at 442. These courts relied on Makripodis v. Merrell-Dow Pharmaceuticals, Inc., in which the Superior Court found that a pharmacist who

properly filled a prescription could not be held liable under an implied warranty of merchantability theory because “the very nature of prescription drugs themselves precludes the imposition a warranty for fitness for ‘ordinary purposes,’ as each individual for whom they are prescribed is a unique organism who must be examined by a physician who is aware of the nature of the patient’s condition as well as the medical history of the patient.” 523 A.2d 374, 377 (Pa. Super. 1987).

In Dougherty, the court performed the same analysis as it did with strict liability claims and similarly concluded that claims of breach of the implied warranty of merchantability based upon manufacturing defects in medical devices are not barred, although claims based on design defects and a failure to warn are barred. 2012 WL 2940727, at *6-7.

Judge Conti cited this rationale with approval in the Killen case. 2012 WL 4498865, at *4. For all of these reasons, Plaintiffs’ claim of breach of the implied warranty of merchantability based upon a manufacturing defect may be maintained, but those based upon a design defect or failure to warn should be dismissed.

The implied warranty of fitness for a particular purpose also arises by operation of law. See 13 Pa. C.S. § 2315. It is “based upon a special reliance by the buyer on the seller to provide goods that will perform a specific use envisaged and communicated by the buyer.” Dougherty, 2012 WL 2940727, at *7 (citation omitted). However, the court determined that all forms of breach of the implied warranty of fitness for a particular purpose are barred based on comment k:

where, as here, a product is considered “unavoidably unsafe,” it would be inconsistent with the policy underlying comment k to find an implied promise by the manufacturer that the product is suitable for a particular purpose and to subject the manufacturer to strict liability for a personal injury resulting from a breach of that implied promise. The same policy considerations that except manufacturers of prescription drugs and devices from strict liability for design and warning defects apply here as well and counsel against imposing liability under an implied-warranty theory.

Id. at *8. Plaintiffs have not separately discussed the implied warranty claims. Nevertheless, a review of the case law indicates clearly that such claims should be treated differently.

Therefore, with respect to Count III, the motion to dismiss should be granted with respect to Plaintiffs' claim of breach of the implied warranty of fitness for a particular purpose and the claim of breach of implied warranty of merchantability based upon design defect and failure to warn claims, but denied with respect to Plaintiffs' claim of breach of the implied warranty of merchantability based upon a manufacturing defect.

Breach of Express Warranties

In Count IV, Plaintiffs allege claims of breach of express warranties. Defendants argue that the allegations are insufficient. Plaintiffs argue to the contrary.

"Under Pennsylvania law, an express warranty arises out of the representations or promises of the seller." Parkinson, 315 F. Supp. 2d at 751 (citing 13 Pa. C.S. § 2313). "An express warranty is created by the seller, inter alia, through any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain." Id. (citation omitted).

Plaintiffs allege that made Defendant made at least twelve separate express warranties through "written literature, advertisements, and representations of its representatives and agents" that relate to the subject implant. (Compl. ¶ 56.) They argue that, because the complaint alleges that Mr. Kline relied upon those representations in selecting the Zimmer implant, "by necessity, in order to rely on those representations Mr. Kline must have seen, heard, read, or knew about them." (ECF No. 18 at 5.) However, courts have rejected such attempts to "infer" from the complaint allegations that are not explicitly stated therein, namely that a plaintiff actually read, heard or knew about "warranties" made publicly in medical device literature to "induce" the

plaintiff to purchase the device. See Yurcic v. Purdue Pharma, L.P., 343 F. Supp. 386, 395 (M.D. Pa. 2004); Parkinson, 315 F. Supp. 2d at 751-52; Kester, 2010 WL 2696467, at *10-11. See also Dougherty, 2012 WL 2940727, at *9 & n.15 (cautioning Dougherty “that she must allege sufficient fact to support an inference that an express warranty was created, including the specific source of the alleged warranty (e.g., a publication or package insert) and the specific statements made); Killen, 2012 WL 4498865, at *5 (granting motion to dismiss breach of express warranty claim without prejudice).

Plaintiffs contend that they have alleged more specific averments than the plaintiffs in the cases cited by Defendants. However, the complaint does not allege that Mr. Kline actually relied on a promise made by Zimmer that was directed to him to induce him to purchase the hip replacement component. Therefore, with respect to Count IV, the motion to dismiss should be granted.

Loss of Consortium Claim

In Count V, Cherrie Kline alleges a loss of consortium claim derivative of Gregory Kline’s claims. Defendants move that the claim be limited to those claims that survive its motion. Plaintiffs have not responded to this argument. With respect to Count V, Defendants’ motion should be granted and the loss of consortium claim should be limited to those claims that remain in the case.

For these reasons, it is recommended that the partial motion to dismiss filed on behalf of the defendants (ECF No. 12), treated as a partial motion for judgment on the pleadings, be granted in part and denied in part, as follows: as to the strict liability claims in Count II, the motion should be granted with respect to Plaintiffs’ design defect and failure to warn claims, but denied with respect to Plaintiffs’ manufacturing defect claim; as to the breach of implied

warranties claims in Count III, the motion should be granted with respect to Plaintiffs' claim of breach of the implied warranty of fitness for a particular purpose and the claim of breach of implied warranty of merchantability based upon the design defect and failure to warn claims, but denied with respect to Plaintiffs' claim of breach of the implied warranty of merchantability based upon a manufacturing defect; as to the breach of express warranties claims in Count IV, the motion should be granted.

Litigants who seek to challenge this Report and Recommendation must seek review by the district judge by filing objections by June 14, 2013. Any party opposing the objections shall file a response by June 28, 2013. Failure to file timely objections will waive the right of appeal.

Respectfully submitted,

s/Robert C. Mitchell
ROBERT C. MITCHELL
United States Magistrate Judge

Dated: May 31, 2013